

**Amendment #1
to RFP-NIH-NIAID-DAIT-02-23**

**"Statistical and Clinical Coordinating Center for Autoimmune Disease
Clinical Trials (SACCC-ADCT)"**

Amendment to Solicitation No.:	NIH-NIAID-DAIT-02-23
Amendment No.:	One (1)
Amendment Date:	March 4, 2002
RFP Issue Date:	January 4, 2002
Issued By:	Barbara Shadrick Contracting Officer NIH/NIAID Contract Management Branch 6700-B Rockledge Drive Room 2230, MSC 7612 Bethesda, Maryland 20892-7612
Point of Contact:	Scott Drega, Contract Specialist
Name and Address of Offeror:	To All Offerors

The hour and date specified for receipt of offers is NOT extended.

The above numbered solicitation is amended as set forth below:

Answers are provided to the following questions:

Question 1. After careful review of the RFP and our initial efforts to draft a proposal, we are quite concerned about the inconsistency between the detailed requirements as specified in the Notes to Offerer and the page limitations of 100 pages including attachments and appendices. Some of the specific concerns are as follows:

--Note 1 indicates that Curriculum Vitae for All proposed personnel should be included in the technical proposal. As the 9 FTE's suggested by the RFP will be spread among 12 to 13 individuals, with CVs in the range of 5 to 12 pages, the full 65 pages allotted to Appendices will be used for CVs.

-- Notes 2, 4, and 6 ask for detailed information about statistical design and analysis (2 and 4) as well as a detailed plan for data collection, management retrieval, quality assurance, and security. The limit of 35 pages is quite constraining relative to such detailed plans.

-- Note 9 asks for substantial details related to drug disposition and specimen repositories. Again, such details as would clearly specify the approach are difficult within the other requirements and the 35 page limit.

Answer 1. The page limits will be increased to not-to-exceed one hundred fifty (150) pages for the narrative portion of the technical proposal with the narrative of the technical approach portion of the proposal not-to-exceed thirty-five (35) pages. Offerors are encouraged to limit Curriculum Vitae to two (2) to three (3) pages of the most relevant experience.

Question 2. Item 5c indicates that the SACCC will provide for "Computerized study forms and systems for the remote entry and transmission of patient data from clinical sites to the central data management facility. . ." Does DAIT anticipate that the use of distributed data entry systems meets this requirement, or is direct data entry to the SACCC using Web-based capture systems a necessary requirement?

Answer 2. Section 5c of the Statement of Work outlines the requirements for entry and transmission of patient data. The section states “Computerized study forms and systems for the remote entry and transmission of patient data from clinical sites to the central data management facility, or alternative non-computerized methods when appropriate.” Therefore, alternative non-computerized methods will be considered, but it is up to you as the offeror to determine which approach will best fulfill the requirements outlined in the Statement of Work.

Question 3. In the Evaluation Criteria, Item 1a under technical approach indicates that statistical leadership is needed for the design and analysis of trials and mechanistic studies for both the Consortium and the ACE, but 1b indicates that clinical trial expertise for design, implementation, refinement, modification, and monitoring is specified only for the Consortium. Based on the items in the Statement of Work, we presume that that exclusion of ACE from this requirement is an oversight, but did want to confirm that.

Answer 3. The Evaluation Criteria 1b will be updated to note that the ACE will be included in 1b.

Page 34 - PAGE LIMITS is amended as follows:

PAGE LIMITS – THE NARRATIVE PORTION OF THE TECHNICAL PROPOSAL IS LIMITED TO NOT-TO-EXCEED ONE-HUNDRED FIFTY (150) PAGES, [INCLUDING: Appendices, Attachments, Operating Manuals, Non-Scannable Figures or Data, Letters of Intent, etc.] WITH THE NARRATIVE OF THE TECHNICAL APPROACH PORTION OF THE PROPOSAL NOT TO EXCEED FIFTY (50) PAGES. ANY PORTIONS OF YOUR PROPOSAL NOT AVAILABLE ELECTRONICALLY ARE ALSO CONSIDERED TO BE INCLUDED IN THE TOTAL PAGE LIMITATION. PAGES IN EXCESS OF THIS LIMITATION WILL BE REMOVED FROM THE PROPOSAL AND WILL NOT BE READ OR EVALUATED.

Page 66 - TECHNICAL EVALUATION CRITERIA PART A. TECHNICAL APPROACH paragraph 1) b) is amended as follows:

b) providing clinical trial expertise for the design, implementation, refinement, modification, and monitoring of clinical trials and mechanistic studies conducted by *the ACE and the Consortium*;

POINT OF CONTACT information on the Cover Page of the RFP is updated to reflect the following correction.

DELETE: Sdrega@niaid.nih.gov

INSERT: SDrega@niaid.nih.gov

Except as provided herein, all terms and conditions of the RFP document NIH-NIAID-DAIT-02-23 remain unchanged and in full force and effect.

Offerors must acknowledge receipt of this Amendment #1, by the following method:

- By acknowledging receipt of the amendment on each copy of the offer submitted.

Failure to receive your acknowledgment of this amendment may result in the rejection of your offer.